

Application Serial No. 10/047,578
Amendment dated November 3, 2005
Reply to Office Action dated May 4, 2005

Listing of Claims

1. (Presently Amended) A composition comprising:

a plurality of active pharmaceutical ingredients, ~~said active pharmaceutical ingredients being~~ consisting essentially of phenylephrine and pyrilamine and being present as a plurality of dosage forms, each of said dosage forms including an amount of said active pharmaceutical ingredients, said amount being generally uniform in each of said dosage forms, when compared one to another, the composition formed from a method comprising the steps of:

- a. forming a solution by dissolving the salt or free base of said active pharmaceutical ingredients consisting of phenylephrine and pyrilamine in a first solvent to form a first solution, wherein dissolving said active pharmaceutical ingredients under conditions that will not cause decomposition of the active pharmaceutical ingredients;
- b. forming a dispersion by mixing a dispersing agent and tannic acid in a second solvent to form a first dispersion;
- c. transferring at least a portion of the first combining the solution and to the first dispersion, to form to form a second solution including tannate salts of the active pharmaceutical ingredients; and
- d. combining substances combining the tannate salts without isolation or purification with at least one suspending agent agents, thickening agents;

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- ~~coloring agents, anti-caking agents, sweetening agents, flavoring agents and pH adjusting agents to form a liquid pharmaceutical carrier; and~~
- e: ~~combining at least a portion of the second solution to the liquid pharmaceutical carrier to produce a suspension liquid dosage form including pharmaceutically active tannate salts.~~
2. (Original) The composition of claim 1 wherein the active pharmaceutical ingredients are present in a range of about 0.05% to about 25.0% by weight.
3. (Presently Amended) The composition of claim 1 wherein the active pharmaceutical ingredients are selected from the group of salts consisting of maleate, citrate, chloride, bromide, acetate, and sulfate, and combinations thereof.
4. (Original) The composition of claim 1 wherein the tannic acid is natural or synthetic.
5. (Presently Amended) The composition of claim 1 wherein the dispersing agent is selected from the group consisting of magnesium aluminum silicate, xanthan gum and cellulose compounds, and combinations thereof.

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6. (Original) The composition of claim 5 wherein the dispersing agent is magnesium aluminum silicate and is present in a range of about 0.05% to about 5.0% by weight.
7. (Original) The composition of claim 1 wherein the tannic acid is present in a range of about 0.05 to about 10.0% by weight.
8. (Original) The composition of claim 6 wherein the magnesium aluminum silicate and tannic acid are present by weight in a ratio in the range of 0.1:1 to 100:1.
9. (Original) The composition of claim 1 wherein the tannic acid and the active pharmaceutical ingredients are present by weight in a ratio in the range of 2:1 to 10:1.
10. (Original) The composition of claim 1 wherein the thickening agent is magnesium aluminum silicate and is present in a range of about 0.5% to about 10.0% by weight.
11. (Original) The composition of claim 1 wherein the suspending agent is kaolin and is present in a range of about 0.5 to about 10.0% by weight.

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12. (Original) The composition of claim 1 wherein the sweetening agents include sucrose present in a range of about 5.0% to about 50.0% by weight, and saccharin sodium present in a range of about 0.01% to about 3.0% by weight.
13. (Original) The composition of claim 1 wherein the flavoring agent is artificial grape and is present in a range of about 0.01% to about 2.0% by weight.
14. (Original) The composition of claim 1 wherein the second solvent is water and is present in a range of about 10.0 to about 75.0% by weight.
15. (Original) The composition of claim 1 wherein said second solvent is glycerin and is present in a range of about 2.5% to about 20.0% by weight.
16. (Original) The composition of claim 1 wherein the preservative is methylparaben and is present in a range of about 0.01 to about 1.0% by weight.
17. (Original) The composition of claim 1 wherein the pH adjusting agent is benzoic acid and is present in a range of about 0.05 to about 1.0% by weight.

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18. (Original) The composition of claim 1 wherein the anti-caking agent is pectin and is present in the range of about 0.5 to about 10.0% by weight.
19. (Original) The composition of claim 1 wherein the pH of said liquid dosage form is in a range of about 3.5 to 6.5.
20. (Original) The composition of claim 1 wherein the pharmaceutically active tannate salts are pyrilamine tannate present at about 30mg and phenylephrine tannate present at about 12.5mg.
21. (Original) The composition of claim 19 wherein said liquid dosage form is a suspension.
22. (Previously Canceled)
23. (Previously Canceled)
24. (Previously Canceled)
25. (Previously Canceled)

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26. (Previously Canceled)

27. (Previously Canceled)

28. (Previously Canceled)

29. (Previously Canceled)

30. (Previously Canceled)

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31. (Presently Amended) A composition comprising:

a plurality of active pharmaceutical ingredients, said active pharmaceutical ingredients being consisting essentially of phenylephrine and pyrilamine, and being present as a plurality of dosage forms, each of said dosage forms including an amount of said active pharmaceutical ingredients, said amount being generally uniform in each of said dosage forms, when compared one to another, the composition formed from a method comprising the steps of:

- a. forming a solution by dissolving the salt or free base of said active pharmaceutical ingredients consisting of phenylephrine and pyrilamine in a first solvent to form a first solution, wherein dissolving said active pharmaceutical ingredient occurs under conditions that will not cause decomposition of the active pharmaceutical ingredients;
- b. forming a powder mixture by mixing a dispersing agent, diluent and tannic acid in a second solvent to form a first powder mixture;
- c. transferring at least a portion of the first solution to the first powder mixture, to form tannate salts of the active pharmaceutical ingredients in a second powder mixture;
- d. adding substances selected from the group consisting of dry binding/matrix forming agents and a binder solution to the second powder mixture in order to form a granulation;

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- e: combining the solution and the powder mixture to form tannate salts of the active pharmaceutical ingredients; and granulation with Combining the tannate salts without isolation or purification with at least one tablet excipient to prepare a granulation including pharmaceutically active tannate salts substances selected from the group consisting of diluent, coloring agents, sweetening agents, hardness-increasing agents, flavoring agents, and excipients; and
 - f: processing the granulation into solid dosage forms.
32. (Presently Amended) The composition of claim 31 wherein the active pharmaceutical ingredients are free bases or salts selected from the group consisting of maleate, citrate, chloride, hydrochloride, bromide, hydrobromide, acetate, sulfate, mesylate, palmitate, and stearate, and combinations thereof.
33. (Previously Amended) The composition of claim 31 wherein the tannic acid is natural or synthetic.
34. (Presently Amended) The composition of claim 31 wherein the dispersing agent is selected from the group consisting of magnesium aluminum silicate, xanthan gum and cellulose compounds, and combinations thereof.

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35. (Presently Amended) The composition of claim 31 wherein the solvents are selected from the group consisting of purified water, ethanol, diethylether, methylene chloride, acetone, and isopropyl alcohol, and combinations thereof.
36. (Presently Amended) The composition of claim 31 wherein the diluent is selected from the group consisting of lactose, microcrystalline cellulose, sucrose and mannitol, and combinations thereof, and is present in a concentration of about 1.0 to about 75.0%.
37. (Presently Amended) The composition of claim 31 wherein the binder solution comprises material selected from the group consisting of corn starch, pregelatinized starch, potato starch, polyvinylpyrrolidone and xanthan gum, and combinations thereof, and is present in a concentration of about 0.1% to about 20.0%.
38. (Previously Amended) The composition of claim 37 wherein the binder solution further comprises a solvent.

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39. (Presently Amended) The composition of claim 38 wherein the solvent is selected from the group consisting of purified water, ethanol, diethylether, methylene chloride, acetone, and isopropyl alcohol, and combinations thereof.
40. (Presently Amended) The composition of claim 31 wherein the dry binding/matrix forming agents are selected from the group consisting of methylcellulose, hydroxypropyl methyl cellulose, ethylcellulose, hydroxypropyl cellulose, xanthan gum and polyvinyl pyrrolidone, and combinations thereof, and each is present at a concentration of about 0.1% to about 20.0%.
41. (Presently Amended) The composition of claim 31 wherein the coloring agents are selected from the group consisting of blue, red, yellow, green, orange, and purple, and combinations thereof, and each is present at a concentration of about 0.01% to about 2.0%.
42. (Presently Amended) The composition of claim 31 wherein the sweetening agents are selected from the group consisting of sucrose, saccharin sodium, xylitol and sucralose, and combinations thereof, and each is present at a concentration of about 0.01% to about 40.0%.

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43. (Presently Amended) The composition of claim 31 wherein the flavoring agents are selected from grape, cherry, orange, lime and strawberry, and combinations thereof, and is present in a concentration of about 0.01% to about 3.0%.
44. (Previously Amended) The composition of claim 31 wherein the dispersing agent is magnesium aluminum silicate and is present in about 0.05% to about 15.0% by weight.
45. (Previously Amended) The composition of claim 31 wherein the tannic acid is present in the range of about 0.05% to about 30.0% by weight.
46. (Previously Amended) The composition of claim 44 wherein the ratio of magnesium aluminum silicate to tannic acid is present in the weight ratio of 0.1:1 to 100:1.
47. (Previously Amended) The composition of claim 31 wherein the tannic acid and the active pharmaceutical ingredients are present in the weight ratio 2:1 to 10:1.
48. (Previously Amended) The composition of claim 31 wherein the tannate salts are pyrilamine tannate present at 30mg and phenylephrine tannate present at 25mg.

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49. (Previously Canceled)

50. (Previously Canceled)

51. (Previously Canceled)

52. (Previously Canceled)

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53. (Presently Amended) A composition comprising:

a plurality of active pharmaceutical ingredients, said active pharmaceutical ingredients being comprising tannate salts and being present as a plurality of dosage forms, each of said dosage forms including an amount of said active pharmaceutical ingredients, said amount being generally uniform in each of said dosage forms, when compared one to another, the composition being formed by a method comprising:

- a: dissolving the salt or free base of active pharmaceutical ingredients selected from the group consisting of consisting essentially of phenylephrine and pyrilamine in a first solvent to form a first solution; wherein dissolving said active pharmaceutical ingredients occurs at a temperature and pH value that will not cause decomposition of the active pharmaceutical ingredients;
- b: mixing a dispersing agent and tannic acid in a second solvent to form a first dispersion; and
- c: transferring at least a portion of the first solution to the first dispersion, to form a second solution including tannate salts of the active pharmaceutical ingredients without isolation or purification.